510(k) Summary

APR 2 1 2014

[As Required by 21 CFR 807.92]

(a)(1)	Submitted By:	Alliance Partners, LLC 14206 Northbrook Dr. San Antonio, TX 78232
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	Date:	Feb 4, 2014/March 31, 2014
	Contact Persons Primary: Secondary:	 Kellen Hills (Orchid Design Consulting) Frank Morris (Alliance Partners, LLC)
(a)(2)	Proprietary Name:	Alamo T Interbody Fusion Device
	Common Name:	Intervertebral body fusion device with bone graft, lumbar
	Classification Name and Reference:	21CFR 888.3080 – Intervertebral body fusion device
	Product Code:	MAX
(a)(3)	Predicate Devices:	Allliance Partners-ALAMO T (K120401) Life Spine-PLATEAU (K111569) Synthes-OPAL (K072791) Surgical Supplies-Biolign (K130274)

(a)(4) Device Description:

The Alamo T device is used for spinal fusion surgery to provide support and structural stability at the fusion site following discectomy. The device is manufactured from PEEK Optima® LT1 per ASTM F2026 and includes tantalum markers per ASTM F560 for radiographic visualization. Supplemental fixation and autograft is required to facilitate fusion.

The device footprint has a hollow center to accommodate bone graft and is implanted via a transforaminal (TLIF) surgical approach. The device is available in various heights and lengths to accommodate variability among patients and the inferior and superior surfaces are designed with ridges to improve fixation and stability and prevent back out and migration.

The purpose of this submission is to introduce a range of line extension sizes and make dimensional modifications to the implants and inserter instrument. The new sizes and design modifications do not affect the device's intended use or alter the device's fundamental scientific technology.

(a)(5) Indications for Use:

The Alamo T device is intended for spinal fusion procedures in skeletally mature patients with degenerative disc disease (DDD) at one or two contiguous levels of the lumbosacral spine (L2-

S1). DDD is defined as back pain of discogenic origin with the degeneration of the disc confirmed by history and radiographic studies. These patients should have had six months of non-operative treatment prior to treatment with an intervertebral cage. In addition, these patients may have up to Grade 1 spondylolisthesis or retrolisthesis at the involved levels. The device system must be used with supplemental fixation and autograft to facilitate fusion and is to be implanted via a transforaminal approach.

(a)(6) Technological Characteristics:

The fundamental scientific technology remains unchanged between the subject and predicate Alamo T devices. Both are interbody devices, designed to contain autograft material and utilize ancillary fixation in order to achieve fusion between two vertebrae. Both subject and predicate devices are made from PEEK with tantalum markers and incorporate teeth on the inferior and superior surfaces to aid in fixation. Both devices utilize instrumentation common to spinal fusion surgery.

Additionally, Life Spine's PLATEAU system was used as a dimensional predicate to validate the new footprints and heights of the subject Alamo T. Sythes OPAL was used as a predicate for graft volume and Surgical Supplies-Biolign was used as a predicate for graft windows.

See table below for a comparison of the subject and predicate devices.

	Subject Device	Predicate Devices	
	Alamo T	Alamo T (K120401)	PLATEAU (K111569)
Product Code	MAX	Same	
Classification	888.3080	Same	
Indications/Intended use	See Sec (a)(5)	Same	
Materials	PEEK Optima LT1 and Tantalum (markers)	Same	
Graft Opening	Large axial window	Same	
Teeth	Superior and Inferior surfaces. Pyramid pattern.	Superior and Inferior surfaces. Pyramid pattern and ridge	
Radiographic Markers	Yes	Same	
Footprint	11mm x 28mm x 0° lordosis 11mm x 32mm x 0° lordosis	11mm x 28mm x 0° lordosis	11mm x 27mm x 0° lordosis 11mm x 32mm x 0° lordosis
Height	6-14mm (11x28) 8-14mm (11x32)	8-14mm	6-14mm (11x27) 8-14mm (11x32)
Sterilization	End User (Steam)	Same	

(b)(1) Non-clinical testing:
A failure modes and effects analysis was conducted to evaluate the impact of the design changes. Consideration was also given to FDA's 2007 Special Controls guidance "Intervertebral Body Fusion Devices". Finite element analysis and engineering rationale were used to demonstrate that the modifications and new sizes did not present a new worst case and that no additional testing was necessary.

(b)(2) Clinical testing:
Clinical testing was not required to demonstrate substantial equivalence in this premarket notification.

(b)(3) Conclusions:
Based on the information provided in this premarket notification, we believe that the subject Alamo T device and associated instrumentation demonstrates substantial equivalence to the identified predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

April 21, 2014

Alliance Partners, LLC
% Orchid Design
Mr. Kellen Hills
Quality and Regulatory Consultant
4600 East Shelby Drive, Suite 1
Memphis, Tennessee 38118

Re: K140303
Trade/Device Name: Alamo T Intervertebral Body Fusion Device
Regulation Number: 21 CFR 888.3080
Regulation Name: Intervertebral body fusion device
Regulatory Class: Class II
Product Code: MAX
Dated: March 31, 2014
Received: April 1, 2014

Dear Mr. Hills:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set

forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Ronald P. Jean -S for

Mark N. Melkerson
Director
Division of Orthopedic Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K140303

Device Name
Alamo T Intervertebral Body Fusion Device

Indications for Use *(Describe)*
The Alamo T device is intended for spinal fusion procedures in skeletally mature patients with degenerative disc disease (DDD) at one or two contiguous levels of the lumbosacral spine (L2-S1). DDD is defined as back pain of discogenic origin with the degeneration of the disc confirmed by history and radiographic studies. These patients should have had six months of non-operative treatment prior to treatment with an intervertebral cage. In addition, these patients may have up to Grade 1 spondylolisthesis or retrolisthesis at the involved levels. The device system must be used with supplemental fixation and autograft to facilitate fusion and is to be implanted via a transforaminal approach.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.

FOR FDA USE ONLY

Concurrence of Center for Devices and Radiological Health (CDRH) *(Signature)*

Anton E. Dmitriev, PhD

Division of Orthopedic Devices

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